Points to Consider

Ongoing SCID studies.

- What additional review should be carried out for ongoing gene transfer studies of x-linked SCID and other types of SCID?
- How should the assessment of the balance of potential benefits and risks in these protocols be modified in light of our understanding of these two cases?
- Which protocols should be recommended to proceed?
- What modifications if any should be made in specific protocols?

Points to Consider

Ongoing other gene transfer studies using retrovirus vectors

- What additional review should be carried out for ongoing gene transfer studies of other conditions involving retrovirus vectors?
- How should the assessment of the balance of potential benefits and risks in these protocols be modified in light of our understanding of these two cases?
- What role does the cell type (eg. hematopoietic cells vs hematopoietic stem cells) have in the assessment of risks and benefits and recommendations for changes to the ongoing protocol?
- Which protocols should be recommended to proceed?
- What modifications if any should be made in specific protocols?

Points to Consider

New gene transfer studies using retroviral vectors

- What new gene transfer studies involving retrovirus vectors should be allowed to proceed?
- What role does the choice of cell type (eg. hematopoietic cells vs hematopoietic stem cells) have in the assessing whether the protocol should be allowed to proceed?
- What additional review procedures or points to consider, if any, should be instituted?

Points to Consider

Informed consent.

- What new information needs to be communicated:
  - to participants in ongoing protocols,
  - to prospective participants in new protocols, and
  - to participants who participated in trials closed to further enrollment and even beyond the protocol defined follow up period?

Points to Consider

How might the risk of leukemia be reduced in gene transfer studies using retrovirus vectors?

- Should there be screening of potential participants for additional risk factors for leukemia or cancer?
- Should exclusion criteria be modified?
- Should there be screening for early detection?

Points to Consider

Should procedures be instituted for more intensive long-term follow-up or banking of specimens to investigate possible future cases of serious complications?